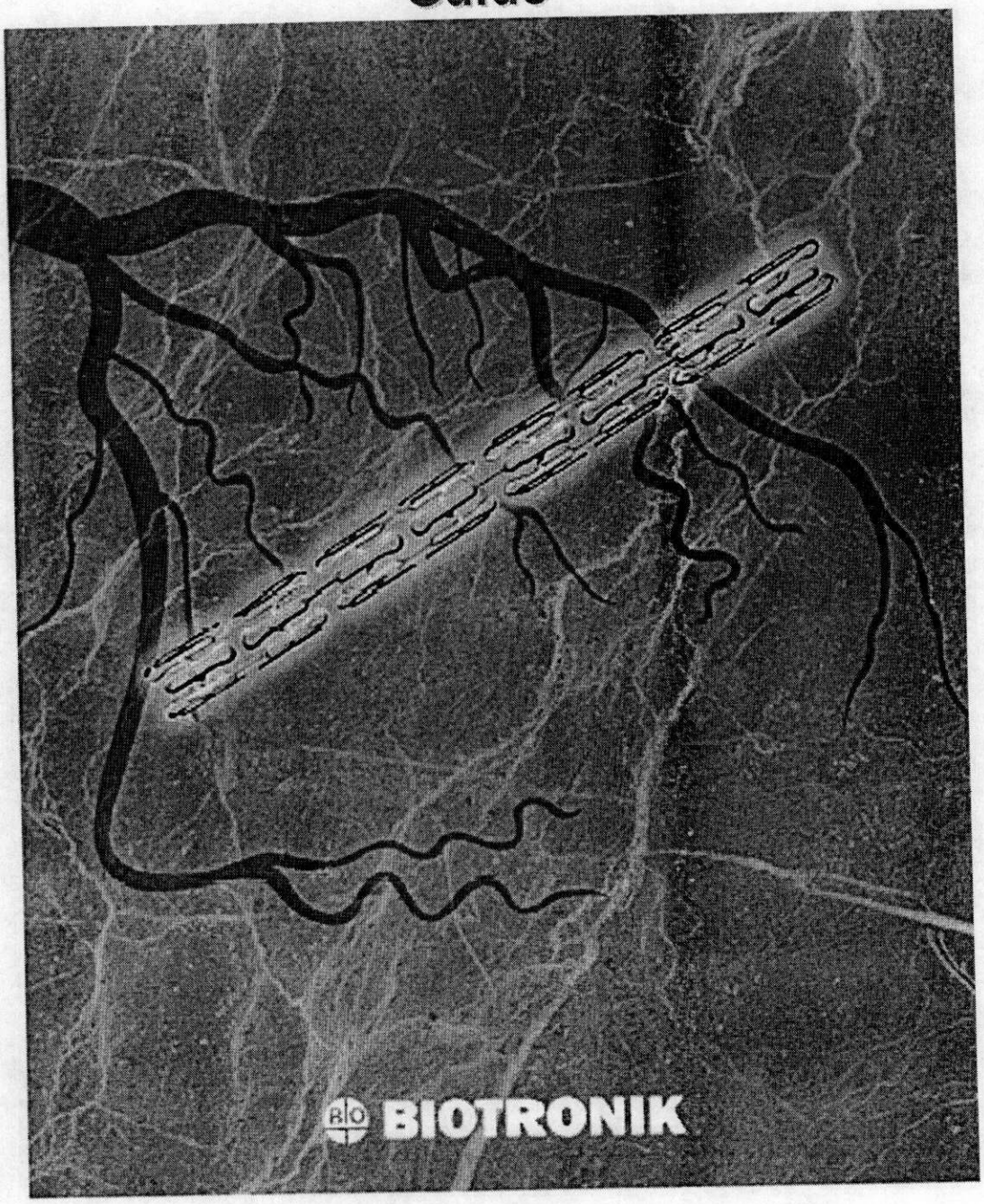
Rithron-XR

Patient Information Guide



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Introduction

You are one of over 13 million Americans who have coronary artery disease, a condition affecting the arteries that supply blood to the heart muscle. However, with proper medical treatment, your condition can be improved.

As a patient who is about to receive a BIOTRONIK Rithron-XR Coronary Stent, we are providing you with this booklet to help answer any of the questions that you and patients like you most commonly ask about your treatment. Your cardiologist should be able to address any additional questions about your stent.

Glossary of terms

Amorphous: Describes a material with no apparent crystalline form

Angioplasty: The dilatation and opening of a coronary artery by using a balloon catheter.

Anticoagulant: A category or drugs that are intended to decrease blood clotting.

Balloon angioplasty: The procedure in which a balloon catheter is placed in the coronary artery to open a closed or narrowed vessel.

Balloon catheter: A catheter with a small balloon that is advanced through the body's arteries to the site of the blockage or closure, where it is inflated to reopen the blocked artery.

Brachial approach: Introducing a catheter into the body at the groin.

Bypass graft: A vein from the leg or an artery from the inner chest wall that is used in surgery to create new routes around narrowed and blocked arteries, permitting increased blood flow to deliver oxygen and nutrients to the heart muscle

Calcium channel blocker: A drug used to treat some cardiac arrhythmias and some forms of chest pain precipitated by oxygen deficiency in the heart muscle

Catheter: A tube used for gaining access to one of the body's cavities or blood vessels. In angioplasty, a catheter provides access to the heart's arteries.

Coronary angiogram: A test used to diagnose Coronary Artery Disease using the catheterization procedure. Contrast dye is injected into the coronary arteries via a catheter, and this allows the doctor to see, on an x-ray

screen, the exact site where the artery is narrowed or blocked.

Coronary stent: A medical device designed to help keep the weakened coronary artery open by acting as a scaffold following balloon angioplasty.

Introducer sheath: The device through which a catheter is inserted into an artery.

Laser etched: To cut a design into the surface of something using a laser beam.

Lesion: A narrowing or blockage that restricts blood flow in an artery.

Magnetic Resonance Imaging (MRI) scan: A diagnostic study similar to a CT or a CAT scan which creates an image using electromagnetic waves instead of x-ray.

Percutaneous approach: Introducing a catheter into the body at the groin.

Silicon carbide: A hypoallergenic medical product used on heart valves and other medical products that potentially reduce thrombus formation.

Stenosis: Narrowing or contraction of a blood vessel.

Stent: An expandable, slotted metal tube inserted into a vessel. A stent acts as a scaffold to provide structural support for a vessel.

Thrombus: A blockage of blood within a blood vessel caused by clumping of cells.

Vessel: Refers to an artery or other blood vessel.

The Heart

Your heart is a hollow muscular organ that beats rhythmically (heartbeat) to circulate oxygen rich blood to all the organs and tissues of your body. Oxygenated blood is delivered to the heart itself through small blood vessels surrounding the surface of the heart called coronary arteries.

Aging, heredity, and diet influence the formation of fatty substances such as cholesterol, which collects on the inner walls of the coronary arteries. This build-up of fatty deposits is commonly known as coronary artery disease or atherosclerosis.

As this build-up continues, the fatty deposit causes the coronary arteries to narrow, slowing blood flow and reducing the amount of oxygenated blood reaching the heart muscle. The lack of oxygenated blood to the heart may result in symptoms such as chest pain or angina.

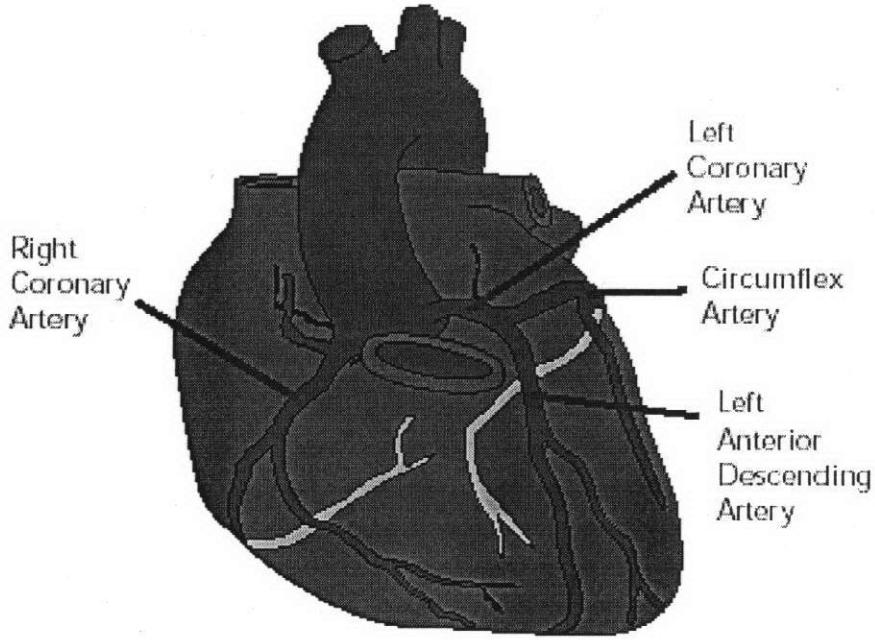

Figure 1: The Heart and its Coronary Arteries

Cardiac Catheterization

After a discussion of your medical symptoms and an examination by your physician or cardiologist, you may need to undergo a cardiac catheterization and coronary angiogram procedure. Using specialized X-ray equipment, this procedure allows the physician to view any narrowing or obstructions within your coronary arteries.

For the coronary angiogram procedure you will be taken into a Cardiac Catheterization Laboratory where specially trained nurses and technicians will prepare you for the procedure. The coronary angiogram is performed in the following manner:

- You will remain awake during the procedure, so you can move or breathe deeply when asked to do so by the doctor. However, you will be given a mild sedative to help you relax.
- EKG electrodes will be placed on your chest to monitor your heart rate and rhythm.
- The site at which a long tube called a catheter will be introduced into your body (either your groin or your arm) will be shaved and cleaned. The approach from your groin is called a percutaneous approach. The approach from your arm is called a brachial approach.
- A local anesthetic, similar to the medication your dentist uses, is injected at the cleaned site to numb the skin prior to inserting the catheters.

- The doctor will make a small incision in the skin through which he/she will insert a guidewire and introducer sheath. (The introducer sheath is a hollow tube that is placed in the artery. The sheath allows for passage of the catheter to the blocked artery in the heart.) A diseased coronary artery with an inserted guidewire is shown in Figure 2.

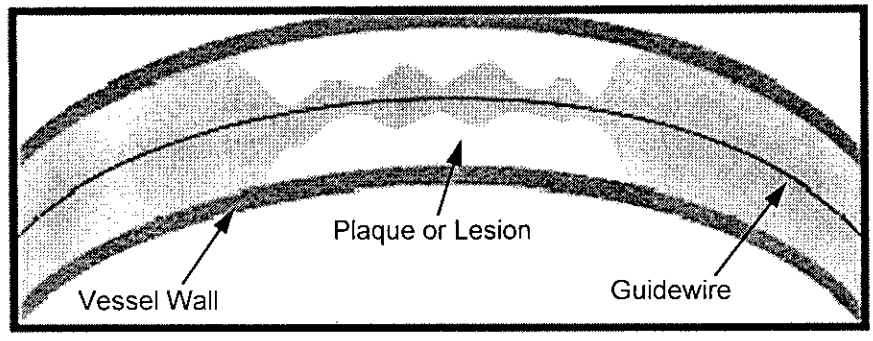

Figure 2: Artery with Plaque

- To visualize the blockage in your coronary arteries as well as the function of your heart muscle, the physician will use a dye or contrast material that is visible using X-ray. This dye will be injected through the catheter that is placed in your coronary arteries. Movie or video cameras will be used to record the injections of dye so that the physician may review them at a later time.
- During these injections, you will be asked to take a deep breath and hold it in while the angiogram is recorded. This will allow the doctor to have a clearer view of your heart on the X-ray screen. You may also be asked to cough after the recording finished in order to assist with clearing the dye from your coronary arteries.

- If the doctor sees a blockage or narrowing during the angiogram, it may be determined that you require a balloon angioplasty. This procedure can be performed in conjunction with the coronary angiogram or at a later date.
- Following the angiogram procedure, you will be transferred to a recovery area for observation and removal of the catheters and sheath. A pressure bandage will be placed over the access site in your arm or groin to assist in stopping the vessel from bleeding prior to being transported back to your hospital room or being released to go home.

Treatment Options for Coronary Artery Disease

Your physician and cardiologist will review the X-ray films taken during your coronary angiogram procedure and determine if there is a narrowing or blockage that requires further treatment. He/she will discuss the results with you and advise appropriate treatment options based on your medical history, individual anatomy, and personal needs. These treatment options may include medication, balloon angioplasty, or coronary artery bypass graft surgery. If balloon angioplasty is appropriate for your coronary disease, you may also be a candidate for a coronary stent.

What is a coronary stent?

A stent is a mechanical tubular apparatus that is positioned across the narrowed or blocked area in the coronary artery and acts as a framework or scaffold that holds up the interior wall of the artery.

A stent, which is made of a material such as surgical-grade stainless steel, is a permanent implant that remains in your artery. **It is important to notify your doctor if you have any known allergies to metals.**

How is a coronary stent implanted?

The stent, which is wrapped tightly around a standard coronary balloon catheter, is inserted into the artery and placed at the site of the blockage (see Figure 3).

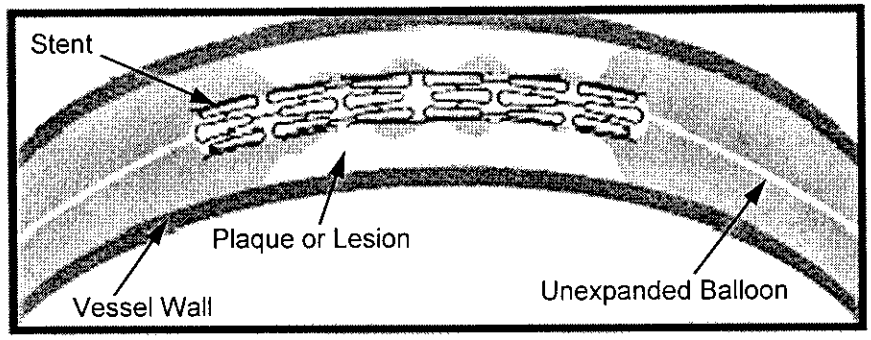

Figure 3: Stent Mounted on Balloon

Once in position, the balloon is inflated to expand the stent. The stent becomes firmly pressed into the inner wall of the artery. (see Figure 4)

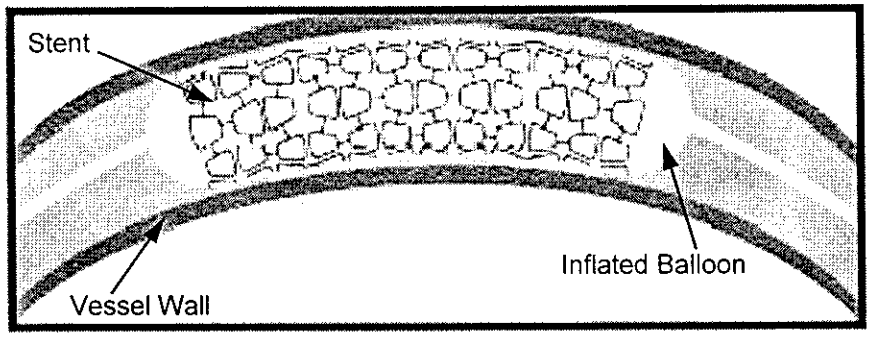

Figure 4: Stent with Balloon Inflated

X-ray pictures are taken so that the doctor can see the stent in your artery. Additionally balloon inflations may be necessary to fully expand the stent. The balloon is deflated and removed along with the guidewire and catheter. The stent remains in place permanently, keeping the artery open (see Figure 5).

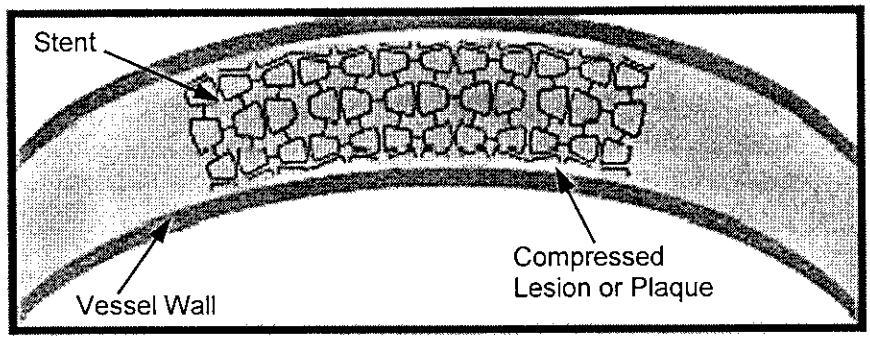

Figure 5: Balloon Withdrawn – Stent Implanted

Why a coronary stent?

Although about 400,000 balloon angioplasty procedures are performed annually in the United States, studies have shown that nearly 30-50% of those patients develop a restenosis or re-narrowing of the coronary artery within 3-12 months. In a small percentage of patients (2-11%), the coronary artery re-narrows or closes soon after the angioplasty procedure (abrupt closure). In these situations, the placement of a stent can often be of benefit by holding open the weakened artery after balloon angioplasty.

Why a BIOTRONIK Rithron-XR Stent?

The BIOTRONIK, Inc. stent is laser etched from a single piece of 316L surgical grade stainless steel. The tubular, slotted design provides flexibility, minimizes shortening after expansion, and provides the radial strength to keep the coronary artery open after placement. The stent is also coated with an amorphous silicon carbide layer for creating a smooth surface. The stent is mounted on a custom balloon delivery system (see Figure 6) for secure fixation during delivery to the lesion site.

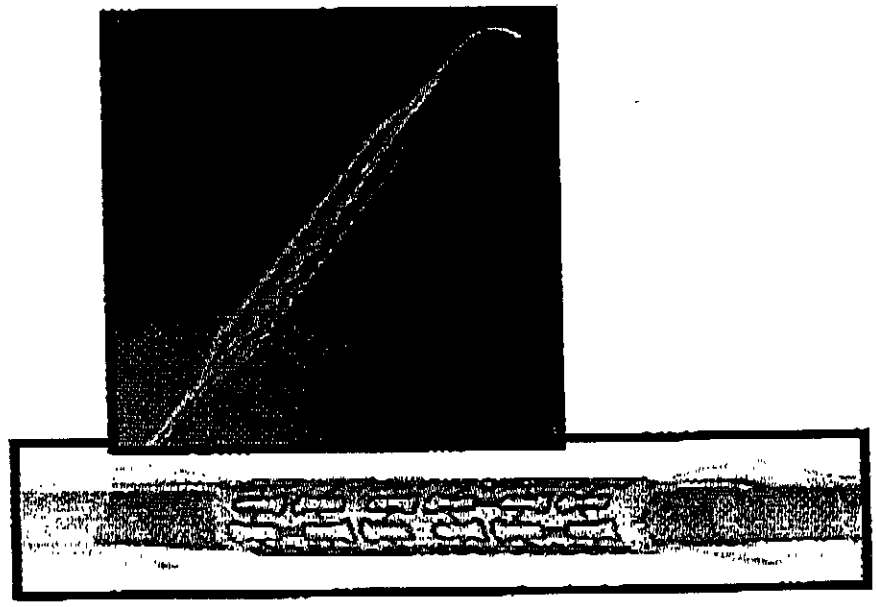

Figure 6: Rithron-XR Stent on Deployment Catheter

Treatment Following Stent Implantation

Your physician or cardiologist will prescribe drugs to reduce the chance of your artery narrowing or closing again. These medications may include aspirin, clopidogrel, ticlopidine, heparin, and/or Coumadin®, based on your individual medical condition. Additionally, you will be given information on long-term follow-up care and what types of activities you should avoid. **It is very important that you continue to take your medications as prescribed by the physician or cardiologist until directed to stop.**

The doctor will also talk with you about other factors that reduce the chance for further coronary atherosclerosis or repeat angioplasty procedures such as:

- reducing the fat and cholesterol in your diet;
- quitting or reducing smoking; and
- controlled exercise on a regular basis.

It is important to keep all scheduled appointments with your physician and/or cardiologist so that he or she can monitor your progress, answer questions, and give you additional instructions.

If at any time you should develop chest pain, discomfort, or bleeding from your incision site, contact your doctor or the emergency room immediately.

Precautions

Because of the blood thinning medications you will be taking after your stent implant, it is important to remember the following precautions:

- **Notify any doctor or dentist treating you for other medical conditions that you have a stent implant.**
- **Avoid taking extra aspirin, Advil®, Motrin®, or any other aspirin or ibuprofen containing products for pain because these may increase the risk of bleeding.**

Questions you may have regarding your stent implant

Question: Is a stent implant a permanent cure?

Answer: In some patients, the artery may re-narrow (called restenosis) despite your stent implant. A physician will discuss other treatment options if this should occur.

Question: What additional medication will I be required to take after the stent implant?

Answer: Your treatment most likely will include taking aspirin as a blood thinning or anti-coagulation agent, as well as a combination of drugs such as ticlopidine, a calcium channel blocker or Coumadin®. Your physician will discuss with you the dosage and time periods required to take these drugs properly.

Question: Should I be concerned about being allergic to the stent?

Answer: The stent is constructed from surgical grade stainless steel coated with a silicon carbide coating. There have been no known or reported cases of allergic reactions caused by a stent. However, people allergic to 316L stainless steel could be at risk for an allergic response. The silicon coating on the stent has been used in medical devices for many years without injury. If you have any further questions, you should discuss them with your physician or cardiologist.

Question: Should I be concerned about having an MRI scan in the future?

Answer: The stent should not move during an MRI scan, but it is not known whether an MRI scan will heat your stent. The steel frame from the stent may cause distortion in the MRI image. For this reason, you should notify the physician or technician of your stent implant prior to the MRI study.

Adverse events associated with stent implant

Please discuss with your physician or cardiologist any questions you may have about potential adverse events. The following is a partial list of adverse events associated with stent implant:

- Heart attack
- Drug reactions
- Arrhythmias including fast or irregular heart rhythm
- Coronary artery bypass surgery
- Coronary artery spasm
- Death
- Obstructed blood vessel
- Obstructed stent
- Excessive bleeding at puncture site
- High or low blood pressure
- Infection
- Anemia of the heart muscle
- Perforation of the implanted blood vessel
- Abnormality of the femoral artery
- Reoccurrence of narrowing of the treated blood vessel
- Stroke

BIOTRONIK

RITHRON-XR CORONARY STENT SYSTEM

Patient Identification Card

INSTRUCTIONS: Carry this card with you at all times and show it to any medical personnel who may treat you. Contact your physician before you have a Magnetic Resonance Imaging (MRI) scan.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

This device has not been evaluated for heating in the MR environment nor to determine if it is safe in MRI systems with field strength greater than 1.5 Tesla.

NAME: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP: _____

PHONE: (_____) _____

IMPLANTING PHYSICIAN: _____

PHONE: (_____) _____

HOSPITAL: _____

FOLLOWING PHYSICIAN: _____

PHONE: (_____) _____

RITHRON-XR CORONARY STENT SYSTEM

MODEL: _____ IMPLANT DATE: _____

ORDER #: _____ STENT MATERIAL: _____

LOT NUMBER: _____ SITE OF IMPLANT: _____

BIOTRONIK

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